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Via Electronic and Federal Express

Attn: Stuart Shapiro, FDA Desk Officer
Office of Information and Regulatory Affairs
Office of Management and Budget
New Executive Office Building
725 17th St., NW
Room 10235
Washington, DC 20503

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: FDA Docket No. 02N-0278, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness & Response Act of 2002

Dear Mr. Shapiro:

The Enzyme Technical Association ("ETA") respectfully submits these comments with regard to the Food and Drug Administration's ("FDA") proposed rule entitled "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness & Response Act of 2002" ("proposed rule") and issued in the Federal Register on February 3, 2003 (68 Fed. Reg. 5428). ETA is a trade association of companies that represent manufacturers and distributors of enzyme preparations in the United States, Canada, and Mexico. ETA has been in existence since 1970 and has taken an active role in assisting in the development of regulations and policies that affect the enzyme industry. Its membership represents a majority of the North American enzyme industry.

Under The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Bioterrorism Act") (Pub. L. 107-188), Congress mandated that FDA promulgate regulations requiring prior notice of imported food shipments that would allow inspection of the shipments at the port of entry.[1] This law, which is codified at section 801(m) of the Federal Food, Drug, and Cosmetic Act ('FFDCA"), requires FDA to implement the prior notification regulations by December 12, 2003. ETA commends FDA's commitment to protecting the U.S. food supply.

[1] *See* Section 307 of the Bioterrorism Act.

However, in FDA's haste to meet the statutory mandate, it has proposed a rule that is unwieldy, overly burdensome, and unlikely, in many respects, to have practical utility in assisting FDA in performing its functions as set forth in the Bioterrorism Act.

Pursuant to the Paperwork Reduction Act of 1995, FDA has invited comments on the following aspects of the prior notification proposed rule:

1. Whether the proposed collection of information is necessary for the functions of FDA, including whether the information has practical utility;

2. Whether FDA's estimate of the burden of the proposed collection of information is accurate;

3. Whether there are ways to enhance the quality, utility, and clarity of the information to be collected; and

4. Whether there are ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques and other information.

ETA addresses these four points in its comments below in the context of the following concerns with the proposed rule. First, ETA believes that FDA's proposed definition of "food" goes well beyond congressional intent, and that it should be narrowed so that prior notification submissions are required for "edible" food only. Second, ETA believes that FDA must explore measures to combine the current U.S. Customs entry process with the prior notification process so as to avoid an unnecessary two-part FDA review of food imports. Third, to assure that FDA resources are properly utilized, FDA should conduct a hazard analysis to determine whether certain food categories or shipment types can be exempted from the prior notification requirements. Fourth, ETA also recommends modifications to the proposed prior notification form and update strategy in order to reduce costs while allowing FDA to perform its functions. Finally, ETA identifies several aspects of the regulation that it believes require clarification.

I. The Proposed Definition of "Food" Expands the Prior Notification Requirement Beyond Congressional Intent and Is Unnecessary to the Proper Performance of FDA's Functions

The Bioterrorism Act requires the submission of a prior notice to FDA of plans to import "an article of food."[2] FDA is proposing a definition of "food" that would appear to extend prior notification requirements well beyond shipments of ordinary edible food, to shipments of food processing aids, both direct and indirect, food contact substances such as food packaging and food processing equipment, substances used on food processing equipment, and components of

[2] *See* Section 307 of the Bioterrorism Act.

such items. However, the statutory provisions and the legislative history indicate that congressional intent does not support a prior notification system that covers the breadth of imports included in FDA's proposed rule.

While no specific limitation is placed on the definition of "food" in the Bioterrorism Act prior notification provisions, ETA believes that qualifying language contained in the statutory food facility registration provisions support its belief that Congress intended to limit the notification provision to edible food. Section 305 of the Bioterrorism Act requires the registration of facilities working with "food for consumption." In qualifying the word "food" with "for consumption" Congress identified its intent to require registration of facilities working with edible food. ETA has provided additional comments on the definition of "food" in connection with FDA's food facility registration proposed rule (See 68 Fed. Reg. 5378 (February 3, 2003)), and it incorporates those comments, as they pertain to the definition of "food" herein.[3]

Further support for narrowing the scope of the term "food" is found in a House of Representatives Conference Report accompanying the Bioterrorism Act ("*Conference Report*").[4] The *Conference Report* specifically states that the prior notification provisions "should not be construed to apply to packaging materials if, at the time of importation, such materials will not be used for, or in contact with, food as defined under section 201 of the FFDCA." *(emphasis added)*. This limitation concerning packaging material is not discussed in the proposed rule. In fact, the proposed rule appears to contradict the *Conference Report* statements by including within the definition of "food" and thus, within the proposed prior notification requirements, "substances that migrate into food from food packaging and other articles that contact food."[5] The *Conference Report* makes clear that Congress does not expect FDA to require prior notification of imports of food packaging material or packaging components where the substances do not have contact with food at the time of importation.

ETA would expect that this congressional logic should also be used to exclude from the prior notice requirement imported processing aids and other food contact items that are inedible in bulk, and have no direct contact with edible food "at the time of import." The intent of the proposed prior notification rule is to improve FDA's ability to detect accidental and deliberate contamination of food, and to deter deliberate contamination. In describing the benefits of the proposed rule, FDA relies on the same five intentional and accidental incidences of food contamination that were relied upon to support the food facility registration proposed rule.[6] As stated in its comments on the proposed food facility registration rule, ETA notes that none of the five incidences involve contamination by food processing aids or food contact items, nor is ETA

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[3] *See* Attachment A. ETA expects that Congress intended both the food facility registration requirement and the prior notice of food imports requirement to share a common definition of "food." FDA appears to support this view based on its application of identical definitions of "food" for the proposed rules addressing these statutory requirements.

[4] H.R. Rep. No. 107-481 (May 21, 2002).

[5] 68 Fed. Reg. at 5430.

[6] *See* 68 Fed. Reg. at 5454; 69 Fed. Reg. at 5409.

aware of such incidences. Thus, it is highly unlikely that these substances pose a contamination threat to the U.S. Food Supply.

Obviously, requiring prior notification submissions for shipments of nonedible items dramatically increases the number of products subject to the prior notice requirement, thereby diluting FDA's investigative resources. ETA believes that any increased safety gained in requiring prior notification of food processing aids and indirect food additives will be negligible, at best. Therefore, ETA calls upon FDA to reanalyze its definition of "food", and to consider narrowing its meaning to assure the establishment of a prior notification system that accomplishes the purpose underlying the Bioterrorism Act, i.e., to adequately protect the nation's food supply through judicious use of limited resources.

II. The Proposed Rule Unnecessarily Creates a Two-Part FDA Food Import Review Process, Thereby Significantly Overburdening the Food Industry

FDA has proposed a prior notification system that would subject food imports to two levels of FDA scrutiny. Currently, FDA learns about food imports through its Operational and Administrative System for Import Service ("OASIS"), which is connected to the United States Customs Automated Commercial System (ACS). When an importer offers a food product for entry into the United States, the required information is filed into Customs' ACS and then forwarded to FDA through OASIS. Based on this information, FDA decides to allow entry of the import or to further review it under section 801(a) of the FFDCA, and this decision is electronically forwarded to the filer. Instead of finding a way to incorporate this 801(a) review into the prior notification requirement, FDA is proposing to view the Bioterrorism Act prior notification requirement as a "pre-entry" submission, separate and apart from the determination made under OASIS, limited to satisfying section 801(m) of the FFDCA. Thus, importers of food will be forced to make two submissions, both of which are costly, quite lengthy and time consuming, and in many cases duplicative, in order to gain entry of a food shipment into the United States.

ETA does not believe Congress envisioned duplicative review by FDA in order to implement the prior notification provisions. Instead, it would be reasonable to expect FDA to incorporate the 801(a) review process within the prior notification program. Clearly, the information being requested in the proposed prior notification form is sufficient to allow FDA to conduct both an 801(a) and 801(m) decision.

III. Intracompany Transfers of Food Components Should be Exempt From the Prior Notification Requirement

The food provisions of the Bioterrorism Act were designed to enhance the security of the U.S. food supply. FDA states that requiring prior notice of imported food shipments should improve its ability to detect accidental and deliberate contamination of food and deter deliberate contamination.[7] Based on the proposed scope of the regulation, FDA expects to receive

[7] *See* 68 Fed. Reg. at 5454.

approximately 20,000 prior notification submissions per day.[8] FDA must seriously consider measures to decrease its review burden in order to achieve its stated purpose of detecting and preventing food contamination.[9] ETA recommends that FDA exempt from the prior notification requirements specific food categories or shipment types that present virtually no risk of contamination.

As to shipment types, FDA should consider exempting shipments of food articles that are transferred between commonly owned facilities (i.e., intracompany transfers). Many multinational companies import products from their non-U.S. facilities directly to their U.S. facilities for further manufacturing, processing, packaging, labeling, or distribution. ETA believes that these intracompany transfers of food products are unlikely to pose food contamination risks because the common ownership of the food product will likely assure a higher level of control over the shipment. Allowing exemptions for certain product types and shipment types such as intracompany shipments would allow FDA to free up limited resources in order to focus on food shipments that pose a higher level of risk. It would also reduce the collection burden on multinational companies who regularly transfer products between commonly owned facilities.

IV. Required Information Elements Should Be Streamlined

In accord with the Paperwork Reduction Act, FDA requested comment on measures to enhance the quality, utility, and clarity of the information to be collected. While ETA strongly believes that FDA should pursue a path that will lead to a single FDA review process, if FDA maintains the currently proposed dual review system, it should significantly revise the proposed prior notification form so as to limit the information collected to the items specifically identified in the Bioterrorism Act. Section 307 of the Bioterrorism Act requires the prior notification submission to provide information on the following:

1. the food article
2. the manufacturer,
3. the shipper
4. the grower, if known at the time of the submission
5. the originating country
6. the country from which the food article is shipped
7. the anticipated port of entry.

Such information could clearly be provided in a simple one-page form. However, the proposed rule details each of the seven pieces of information in a manner that has resulted in the development of a complicated 5-page form. Completion of the proposed form's "product identity" section alone will require submission of the complete FDA product code, the common

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[8] 68 Fed. Reg. at 5434.

[9] FDA has a responsibility to promulgate regulations for the efficient enforcement of the FFDCA. *See* Section 701 of the FFDCA. *(emphasis added)*

or usual or market name, the trade or brand name, the quantity, and the lot or code numbers or other identifiers. While not even listed within the "product identity" section of the proposed form, FDA also proposes to require the submission of the U.S. Customs ACS entry line number, which consists of the entry number, the U.S. Customs ACS line number, and the FDA entry line number. FDA acknowledges that most of the proposed information elements are already required as part of the U.S. Customs entry process, thereby confirming the redundant nature of the proposed prior notification strategy. If FDA genuinely plans to treat the prior notification process as a "pre-entry submission," it would seem that a more cursory review should be employed. Thus, ETA strongly recommends reducing the information requirements significantly.

To start with, ETA proposes that FDA make a decision on which code number (i.e., the FDA product code or the U.S. Customs ACS entry line number) best identifies the food article for purposes of complying with section 801(m) of the FFDCA, and rely on one, instead of two codes, to identify the product. In addition, ETA questions the need for phone, fax, and email address information for each party identified on the form. As for both the manufacturer and shipper information sections, it would seem that the name of the firm and its FDA registration number would be sufficient to provide FDA with the information necessary to quickly identify these parties.

ETA also suggests that the prior notification electronic filing system allow the submitter to easily duplicate information that is common to more than one section of the form. For example, it is possible that the manufacturer and the shipper will be the same company. Thus, the form should allow the submitter to repeat the manufacturer information in the shipper section.

V. The Proposed Update Time Frame is Unrealistic and Overly Burdensome

So that FDA has current anticipated arrival information, it is proposing to require updated anticipated arrival information if the previously reported information changes. FDA is proposing that if the time of arrival is more than 1 hour earlier or more than 3 hours later, the anticipated arrival time must be updated. Updates must be submitted no later than 2 hours prior to arrival. [10]

ETA believes that the proposed time frames for updates are unrealistic, unnecessary, and likely to result in frequent submitter errors. Submitters are not in control of the food shipment, and thus, they will be required to rely on shipper information for purposes of submitting the updates. Such tight time frames will also increase the cost of the notification process as the submitter will be forced to continuously check up on the status of the shipment to assure that the arrival time is correct all the way up to two hours before delivery. ETA members believe that many facilities will need to hire a full time employee just to meet the proposed update requirements. As a result, ETA recommends that FDA remove the requirement to submit updates for arrivals.

VI. FDA Estimates of the Costs Associated With the Collection of This Information are Grossly Underestimated

[10] *See* 68 Fed. Reg. at 54.39.

FDA believes that the cost of electronically completing the prior notification submission will be about $33.02 per entry. In discussions with their brokers and importers, ETA members have learned that such an estimate is grossly underestimated, and that, in fact, each submission will likely cost $100.00 or more, given that much of this work will be outsourced to import brokers who currently charge at least $100.00 per import for their services. Further, as stated above in section V, FDA has failed to consider the costs associated with tracking the shipment in order to comply with the update requirement.

Moreover, FDA has not carefully considered the costs resulting from a shipment "hold" for failure to meet the prior notification provisions. Because the Bioterrorism Act will not allow release to the importer of the held shipment under a basic importation or entry bond, the importer, owner, or consignee will be responsible for the cost of storing the product as specified by FDA. ETA expects that even short term holds, possibly resulting from inadequate update information, could result in special warehousing costs that are two to three times the normal warehousing costs, and as these warehouses fill-up, costs will escalate.

VII. Request for Clarification

Several aspects of the proposed prior notification rule raise questions that ETA believes should be clarified in the final rule. For example, ETA members that import product into the United States frequently receive several different enzymes types within a single shipment. As the products all fall within the category of "enzymes," ETA would expect that only one prior notification submission would be necessary even where five different enzyme products were involved. This procedure would be consistent with current U.S. Customs entry processes, which allows for the combination of several enzyme products into one entry. If FDA requires otherwise, it will significantly increase the cost of imports and be a change in current import practice. ETA requests clarification on this issue.

ETA also requests clarification on how FDA characterizes enzyme producers. The process of "manufacturing" enzymes involves the fermentation of specially selected nonpathogenic, nontoxigenic strains of microorganisms, as well as extraction from plant or animal sources. The language used to describe enzyme production frequently mirrors agricultural terms (e.g., harvesting, culturing, fermenting). While ETA members believe that commercial enzyme production is best described as "manufacturing," it requests clarification on the scope of the term "grower" for purposes of completing the prior notification submission. Assuming that enzyme producers should be identified in the "manufacturer section" of the proposed form, ETA asks whether it must identify the facility providing the microorganisms, or plant or animal sources as a "grower."

Further, the proposed form contains a "Cancel this Submission" section with a box to check "yes" and a box to check "no." ETA requests clarification on when it would be necessary to check "no" on this form.

Finally, ETA requests clarification on whether prior notification submissions are required when carriers enter the U.S. with food shipments only for the purpose of refueling and exiting. ETA would expect that if the shipment is not unloaded from the carrier, there would be no need to submit a prior notification submission.

ETA again thanks FDA for the opportunity to comment on the proposed prior notification requirement. ETA wholly supports practical measures to increase public health protections and looks forward to working with FDA to achieve this end without unduly interfering with the U.S. food supply.

Respectfully Submitted,

Jack Harris
Chair

Attachment